



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

21 11 11 03 28 12:25  
APR 16 2004

Mr. Emil Chiaberi  
Chief Executive Officer  
Spirit Sciences USA, Inc.  
6733 S. Sepulveda Boulevard  
Suite 108  
Los Angeles, California 90045

Dear Mr. Chiaberi:

This is in response to your letter of February 23, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Spirit Sciences USA, Inc. is making the following claims, among others, for the product **RU-21®**:

“Acetaldehyde is a toxic byproduct of alcohol metabolism that has been linked to both, most alcohol related injuries and the addictive process  
“Prevents hangovers”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases (i.e., chronic diseases associated with overuse of alcohol, alcohol addiction, and the consequences of alcohol poisoning/overdose (i.e., hangover)). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

LET 749

Page 2 - Mr. Emil Chiaberi

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', followed by a horizontal line.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Spirit Sciences USA, Inc.  
Emil Chiaberi  
Chief Executive Officer  
6733 S. Sepulveda Blvd., Suite 108  
Los Angeles, CA 90045  
(310) 568-1030 Fax: 861-5612

MAR 09 2004

February 23, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.  
Washington, DC 20204

Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

Spirit Sciences USA, Inc. of 6733 S. Sepulveda Blvd., Suite 108, Los Angeles, CA 90045, who is the distributor of the following dietary supplement product, intends to make the following statements of support for RU-21 Dietary Supplement: "Naturally supports the body's ability to metabolize alcohol"; "Supports morning energy"; "Supports healthy skin"; "Promotes healthy DNA", "Supports Reproductive Health".

These claims are being made for succinic acid, fumaric acid, L-glutamine, glucose and vitamin C, which are contained in RU-21 Dietary Supplement. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the Spirit Sciences USA, Inc. and certifies that the information contained in this notice is complete and accurate, and that Spirit Sciences USA, Inc. has substantiation that the above statements are truthful and not misleading.



Emil Chiaberi  
Chief Executive Officer

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# Old Claim

100%  
SAFE AND EFFECTIVE

**SUPER  
VALUE**  
10 Servings  
Inside!

**100%  
SAFE AND EFFECTIVE**

**SUPER  
VALUE**  
10 Servings  
Inside!

**MAINTAIN YOUR HEALTH**

Natural oxidation processes may cause some tablets to acquire a slightly brown color. Change in color does NOT affect the product's potency.

**ABOUT ACETALDEHYDE**  
Acetaldehyde is a natural byproduct of alcohol metabolism. It is the substance that causes the "hangover" feeling after drinking alcohol. Acetaldehyde is also a known carcinogen.

**Supplement Facts**

Serving Size: 2 Tablets	Amount Per Serving	% Daily Value
Servings Per Container: 10	10 mg	20%
Acetaldehyde	200 mg	40%
Choline	20 mg	40%
Total Value of Ingredients		

**SUGGESTED USE:** Take 2 tablets daily with food.

**Other Ingredients:** Cellulose, Stearic Acid, Magnesium Stearate, Polyethylene Glycol, Talc.

**Distributed by Spirit Sciences USA, Inc.,  
9454 Wilshire Blvd.,  
Suite 600, Beverly Hills, CA 90212**

**U.S. Patent Pending**

KEEP IN A COOL, DRY PLACE  
SHELF LIFE 2 YEARS

CLINICALLY TESTED  
REGULATES ALCOHOL METABOLISM

100%  
NATURAL

20 TABLETS  
Net Wt. 10.00 g (0.353 oz)

Сделано в РФ. Оригинально для Spirit Sciences USA, Inc.  
Биологически активная добавка к пище "А-101"  
Регистрационное удостоверение ЛРО02024 Р.543.13.2020  
от 12.10.2020. Министерство здравоохранения РФ  
Made in RF exclusively for Spirit Sciences USA, Inc.

Exp. Date 09/16/20  
Lot # 000000

# New Claims

Клиент в Р.О. Соединенные Штаты Spirit Sciences USA, Inc.  
 Единственный авторизованный дистрибутор "Алти"  
 Перепродажа и экспорт запрещены №7739.11 9285.00627 38.03  
 от 23.08.2004. Импортация запрещена Р.О.  
 Made in RF exclusively for Spirit Sciences USA, Inc.

CLINICALLY TESTED

## ALCOHOL METABOLISM

NATURALLY SUPPORTS THE BODY'S ABILITY TO METABOLIZE ALCOHOL

SUPPORTS

SUPPORTS

SUPPORTS

SUPPORTS

**Morning Energy\***

**Healthy Skin\***

**Healthy DNA\***

**Reproductive Health\***

100%  
NATURAL

**20 TABLETS**  
Net Wt. 1.84 (0.353 oz.)

\*These claims have not been evaluated by the FDA.  
 This product is not intended to diagnose, cure, treat, or prevent any disease.

Contains 400 mg each, yeast (inactive), preservatives, or additives of any kind.

**KEEP IN A COOL, DRY PLACE**  
**SHELF LIFE 2 YEARS**

**10**  
**SERVINGS**  
**VALUE**  
**SUPER**

Portion of proceeds from the sale  
 of this product goes to support National  
 Committee Against Drunk Driving and important alcohol research programs

**HELP FIGHT ALCOHOLISM**  
**AND DRUNK DRIVING**

**10**  
**SERVINGS**  
**VALUE**  
**SUPER**

## MAINTAIN YOUR HEALTH

**Supplement Facts**

Serving Size 2 tablets

Servings Per Container: 10

Amount Per Serving	% Daily Value
Vitamin C	50 mg 63%
Succinic Acid	200 mg
Fumaric Acid	75 mg
L-Glutamine	200 mg

Daily Value not established

Other ingredients: Glucose (Dextrose)

**SUGGESTED USE:** Take 2 tablets 2-3 times a day, after meals, with or without food.

Two tablets a day is the recommended dose.

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Natural oxidation processes may cause some tablets to acquire a slightly brown color. Change in color DOES NOT affect the product's potency.

### ABOUT ACETALDEHYDE

Acetaldehyde is a toxic byproduct of alcohol metabolism that has been linked to both most alcohol related injuries and the addictive process itself.

**Distributed by Spirit Sciences USA, Inc.**  
**9454 Wilshire Blvd, Suite 600**  
**Beverly Hills, CA 90212**  
**URL: WWW.RU21.COM**

**Exp. Date NOV 2006**  
**Lot #: 02/1204**